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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/453,350	05/30/1995	CARL-HENRIK HELDIN	0054.009	6246
27476	7590	09/17/2003		
Chiron Corporation Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097			EXAMINER	SAOUD, CHRISTINE J
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/453,350	HELDIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 May 2003.

2a) This action is **FINAL**.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 25-27 and 43-66 is/are pending in the application.

4a) Of the above claim(s) 46-54 is/are withdrawn from consideration.

5) Claim(s) 27,45,60,62 and 65 is/are allowed.

6) Claim(s) 25,26,43,44,55,56,61 and 64 is/are rejected.

7) Claim(s) 57-59,63 and 66 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

The Decision by the Board of Patent Appeals, dated 30 May 2003, is noted. However, upon updating the search of prior art in the patent database, a new patent reference was discovered.

### ***Status of Claims***

Claims 25-27 and 43-66 are pending in the instant application. Claims 25-27, 43-45 and 55-66 were on appeal and are now the subject of the instant Office action. Claims 46-54 remain withdrawn as they are directed to a non-elected invention.

### ***Claim Objections***

The instant claims contain some inconsistencies which were not identified prior to appeal. They are as follows:

Claim 57 is a duplicate of claim 56. This error could be the result of a typographical error indicating claim dependency. However, it currently is a duplicate and should be amended or canceled.

Claim 63 depends from a canceled claim (28). Claim 66 ultimately depends from claim 28 (canceled). Again, this could be the result of a typographical error in claim dependency, but the error needs correction.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 25-26, 43-44, 55-56, 61, 64, are rejected under 35 U.S.C. 102(e) as being anticipated by MURRAY et al. (U.S. Pat. No. 6,004,929).

The instant claims are directed to a recombinant protein preparation comprising PDGF A-chain homodimer, wherein each PDGF-A chain comprises amino acids 87-193 of Figure 1, or an analog that comprises “less than 10 amino acid variations”, wherein the protein is biologically active and free of other human proteins. The instant specification defines amino acid variations as including substitutions and/or deletions (see page 6, lines 25-27).

MURRAY et al. describe a PDGF A-chain homodimer having 104 amino acids, which are identical to amino acids 87-190 of the claimed A-chain. The PDGF A-chain homodimer of MURRAY et al. is free of other proteins of mammalian origin (see claim

19 at column 28) and is biologically active (see column 27, Table 3). This disclosed protein anticipates the instant claims because it is a species of the genus which is claimed (PDGF A-chain homodimer comprising amino acids 87-193 of Figure 1 with 3 deletions at the C-terminus). MURRAY et al. additionally describe therapeutic compositions for the purposes of wound healing (column 10, line 63 to column 11, line 18), meeting the limitations of claims 43-44 and 55-56.

It is noted that Applicant's filed a 131 Declaration in paper #30 (filed 10 April 1997) in order to antedate an earlier rejection based on a MURRAY et al. patent. However, this Declaration is not sufficient to overcome the new ground of rejection, which is based on the patented claims of MURRAY et al. The rejection cannot be overcome by an affidavit or declaration under 37 CFR 1.131, but only through interference proceedings. MPEP 2308.01 is applicable in the instant situation regarding claims to common subject matter when the Patent has an effective filing date earlier than the application. When the effective filing date of the application is more than 3 months after the effective filing date of the patent, 37 CFR 1.608(b) requires that the Applicant must file (A) evidence, such as patents, publications and other documents, and one or more affidavits or declarations which demonstrate that Applicant is *prima facie* entitled to a judgment relative to the patentee, and (B) an explanation stating with particularity the basis upon which the Applicant is *prima facie* entitled to the judgment.

Alternatively, amendment to the claims, supported by the disclosure of the instant specification, which defines over the claims of MURRAY et al. may also overcome the

rejection of record. For example, if the claims were limited such that deletions were not encompassed, this would overcome the rejections based on MURRAY et al.

***Allowable Subject Matter***

Claims 27, 45, 60, 62, 65 are allowed.

Claims 58-59 are objected to for dependence on a rejected claim, but would be allowable if rewritten in independent form, including the limitations of the base claim.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 703-305-7519. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CHRISTINE J. SAoud  
PRIMARY EXAMINER  
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